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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,408	10/05/2004	Jens Tonne Andersen	10295.204-US	9822

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NEW YORK, NY 10110

EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/510,408

Applicant(s)

ANDERSEN ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-40 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/5/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 22-40 are pending in the case.

Receipt of the Information Disclosure Statement filed 10/5/04 is acknowledged.

Election/Restrictions

Applicant's election of Group I, claims 22-40 only as directed to SEQ ID NO:2, in the reply filed on 5/5/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants should cancel those portions of the claims which refer to SEQ ID NOs: 3-191.

Claim Objections

Claims 22-40 are objected to because of the following informalities: the claims currently recite "one or more gene(s) encoding one or more polypeptide(s) involved in sporulation which are at least 80% identical to one or more of the polypeptides shown in SEQ ID NO:s:2 to 191", and other phrases referring to one or more polypeptides. The claims have been restricted to *B. licheniformis* host cells mutated in a gene encoding a polypeptide which are at least 80% identical to the polypeptide shown in SEQ ID NO:2, and a method of use of said cells.. Therefore, the claims should be amended to refer to only one polypeptide. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 22 is drawn a *B. licheniformis* mutant host cell "derived" from a parent host cell which is mutated in the gene encoding the polypeptide involved in sporulation which is at least 80% identical to the polypeptide shown in SEQ ID NO:2, wherein the mutant host cell expresses at least 5% less of said polypeptide "involved in sporulation" than the parent host cell when cultivated under comparable conditions. Claim 39 is drawn to a process for producing a product of interest comprising cultivating said host cell to product a product of interest. The specification does not define what is meant by the phrase "involved in sporulation", and the claim has been given the broadest reasonable meaning. Claims 22-40 are genus claims in terms of a *B. licheniformis* host cell and method using said host cell which has any mutation in any polypeptide having at least 80% identity to SEQ ID NO:2,

Art Unit: 1636

wherein at least 5% less of said polypeptide are produced. The specification has provided no information on the function of the polypeptide whose sequence is disclosed in SEQ ID NO:2, other than the involvement in sporulation, or of any particular region or amino acids thereof which have any significance to this function of the polypeptide.

The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the mutant host cells having mutations in genes encoding polypeptides which have at least 80% identity to SEQ ID NO:2, and which are involved in sporulation. The prior art does not remedy this lack of disclosure, since a sequence search of the amino acid sequence disclosed in SEQ ID NO:2 did not result in any sequences having significant, or greater than 80% homology. Furthermore, the polypeptide of SEQ ID NO:2 is not disclosed as being a member of any well-known and described family of polypeptides or enzymes, which share common structural elements and functions. The specification provides no information provided regarding the precise amino acids, or even which general regions of the polypeptide whose sequence is shown in SEQ ID NO:2, can be altered, and remain involved in sporulation. There is no structure-function analysis of the disclosed polypeptide shown in SEQ ID NO:2 that could be modified and retain function in sporulation. Therefore, the specification does not describe the claimed mutant host cells comprising mutations in genes encoding polypeptides having at least 80% identity with SEQ ID NO:2 and which are involved in sporulation, in such full, clear, concise and exact terms so as to indicate that Applicant

has possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22, and by dependence claims 23-40, are vague and indefinite in the recitation of the phrase 'derived from' a parent *B. licheniformis* host cell. "Derived" is a term that is non-specific and relative in nature for which Applicant provides no definition. It provides no clarity as to what Applicant's claimed invention includes and what it does not include. Without a more specific definition, it is impossible to determine what and how many derivations comprise the invention. The nature and number of the derivations to arrive at the invention Applicant seeks to protect with the patent are not established such that a person skilled in the art would be apprised of the metes and bounds of the claims. The limits of the inventions cannot be discerned and others could not know if they were infringing Applicant's claim. The claim is further indefinite in the recitation of "involved in sporulation" since it is not clear what is intended to be encompassed by this phrase and therefore the metes and bounds of the claimed subject matter cannot be determined.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
6/7/06


NANCY VOGEL
PRIMARY EXAMINER